DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 14(18), 2687-2703 (1988)

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EQUIPMENT SELECTION FOR THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

The selection process involving equipment for use in the pharmaceutical industry is discussed. A protocol is outlined to assist the evaluator in making the optimum choice for the application. A model is presented which helps the user combine dissimilar evaluation factors in a single framework.

RATIONALE

Acquiring new technology through the selection and implementation of new manufacturing equipment has strategic implications for all companies. What eventually is purchased, how much is invested, and the timing of the transaction are factors which will have both a financial as well as strategic impact on the corporation. The outcome of the selection process has a direct influence on the success of a production facility through reducing costs, improving quality or safety, or reducing environmental concerns. Within a short period of time the selection process will affect profitability, eventually improving or reducing the value of the firm. Because of this impact the purchase of new equipment should

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be viewed as acquiring strategic resources and should be carried out by a full-time technical staff.

The strategic goal in acquiring new equipment may be as straightforward as acquiring technology that best meets the needs of the corporation for the least cost. The actual selection process is much more intricate and is best accomplished by a centralized, dedicated team who can evaluate, select, and implement new equipment technologies for the firm. This team will eliminate redundancy and improve consistency in the evaluation methods. But these reasons fall far short in justifying the groups existence and expense. More importantly, current pharmaceutical technologies are highly specialized, fragmented, and in some cases obsolete within a short period of time. This mandates the use of technology gatekeepers who stay abreast of activities inside and outside of the firm. These technology gatekeepers will be instrumental in keeping the firm competitive through the acquisition of new equipment in a methodical manner.

INTRODUCTION

The selection of a vendor, although an item of critical importance, does not always receive the detailed attention as do most processes in the pharmaceutical industry. Where procedures for manufacturing, cleaning, and validation have detailed "Standard Operating Procedures" strictly specifying how an operation is to be performed, the method by which a vendor and their equipment is evaluated and chosen is often left up to the individual. Although the success of a project can often depend upon making the correct choice, there are usually no written guidelines by which

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to evaluate new equipment. Many times the only guideline followed is the submission of three bids to management with a recommendation for the chosen vendor. If the reviewers of the proposal are not familiar with the equipment in question, it can be difficult for them to find discrepancies in the reasoning of the evaluator. The result can be owning equipment that is not the optimum choice for the application. Having an outlined procedure by which to examine and evaluate prospective equipment will help keep the purchasing reasons in focus and the decision making process methodical.

DISCUSSION

The critical first step when purchasing equipment is to establish a set of goals concerning what is to be achieved by the acquisition. Increasing production, reducing operating costs, or the building of a new manufacturing facility are all examples of these goals. It is imperative that this direction be set for the entire project. The project goal may have more than one solution and the choice will only be narrowed with the influx of information acquired from the evaluation. Evaluators should be open-minded and consider alternative ways of achieving their goal. If, for example, a project goal is to double the production rate of a packaging line consisting of older equipment, two possibilities may exist. One could be the addition of new equipment to the existing line which would increase production to the level required. Another solution could be to completely replace all the equipment with state of the art, high speed equipment capable of the output of the other two lines combined. At this time, a

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direct comparison of this equipment with others might not be feasible as the equipment may not share sufficient areas of similarities to give the comparison validity. So at this early stage more than one alternative solution can exist, although they should be few and must be clearly defined. It is important, however, that parallel sets of parameters be defined between the coexisting solutions, so these solutions can be ultimately compared to each other. This comparison, combined with a final cost analysis of the chosen vendor for each possible solution, can determine the direction that is most economical and practical to take.

When establishing these goals it is important to specify who should be involved in the decision. The evaluation group's composition will depend upon the size, structure, management philosophy, and strategic direction of the firm, as well as, how technology-intensive the competing industry is. A typical group involved in the evaluation process would be representatives from the plant acquiring the equipment, corporate and facilities engineering, and process development personnel. They will follow the procedures established to determine the best overall supplier and equipment.

With the goal(s) of a project established, the group of individuals responsible for evaluation must then establish preliminary specifications for each type of equipment to be evaluated. Approximate output rates must be determined so vendors' quotations at this initial stage will be based on a consistent set of parameters. Only those capable of meeting the requirements of

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the project will be asked for bids. Whether qualification and validation can be satisfied should also be a determining factor. This will save time by not evaluating equipment incapable of meeting the proposed requirements.

With preliminary requirements set, it is time to establish a group of vendors capable of manufacturing the equipment to meet these specifications. Traditional, as well as, new vendors, should be welcome at this early stage. This can make one aware of a previously unknown source, and also, increase the responsiveness of traditional suppliers. Established vendors will become more responsive with the knowledge of additional competition.

Vendors should be asked to visit at this point in time. These sales calls should be encouraged to review preliminary specifications and to let the vendors present their qualifications. Budget quotations within ten percent should be submitted. Any important requirements that are unique to the particular application should be stressed. If, for example, a filling or packaging line is going to be installed in a third world plant, simplicity and service are going to be just as important as output capabilities.

From this large group of vendors a more limited group of three to five vendors should be chosen. It is possible there are few vendors who manufacture a specific type of equipment. If this is the case, as often is with highly specialized machinery, this step would be eliminated. At this very early stage the vendors that have bid on the proposal can be evaluated qualitatively. How quickly did they respond to the proposal requests? Do they seem

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eager for your business? The degree of responsiveness at this stage is often indicative of the service that can be expected after purchase. Did vendors seem knowledgeable during their sales calls? Were they well prepared for their visit? The answers to these questions will help decide if a vendor is capable of producing equipment to meet your requirements. It is also important to compare the budget quotations. Are there any bids priced much higher or lower than average? An inordinately low price should cause as much concern as an excessively high one. A vendor may have mistakenly been quoting unneeded expensive options, where another quotation may be lacking aspects that are critical to your operation.

After the field of competing vendors is narrowed, a formal evaluation using finalized equipment requirements must be performed. It is possible certain alternative solutions may have been eliminated with the preliminary knowledge gained in the first round of vendor evaluation. If this is the case, those solutions remaining must have specific production requirements which can be supplied to vendors for quotation. It is also important for them to describe their services and the associated costs concerning field service, parts, training programs, etc. At this time, the degree of difficulty in qualifying and validating this equipment should be scrutinized. Qualification and validation problems often entail hidden expenses that will eventually be added to the cost of installing the equipment.

A critical step, often left out, is to have a written protocol by which to evaluate the equipment. This protocol should

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define and prioritize the requirements the proposed equipment and vendors should meet and define a method by which to quantify these variables. With a set document or model, the vendors will each be given an equal evaluation which gives the decision making process more validity. Later in the presentation one such model is discussed.

To initiate this evaluation protocol, the examination of the remaining vendors and their equipment must by arranged. Formal bid packages using the agreed upon specifications must be sent to the manufacturers. Visits to the manufacturer's facility can be most helpful in determining their actual capabilities as well as their attitude towards their customers. It is important to observe the state of their manufacturing facilities. Are there idle machines or is the plant busy? Does there seem to be equipment in various stages of production or is it in limited areas? These observations will provide some insight into how well this equipment is selling. Some manufacturers have laboratory models that can be used for evaluation. If this is possible, take full advantage of this capability as it can be invaluable. If time permits renting the equipment can serve the same purpose but to a much greater extent. Using the equipment is the best way to foresee potential problems. The rolled-up shirt sleeves approach is the only way to assure attaining a thorough understanding of a machine's finer points. Standing by watching the vendor's technicians run the test will allow many of the subtle details to be missed.

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If samples of a product are to be used during test runs it is very important they be representative samples of the final product. For example, different sizes of a package can cause large variations in output rate. The manufacturer will be agreeing to performance requirements based upon the information supplied at this stage. If there are changes at a later date, these changes may cause rework which can be expensive.

After completing the evaluation according to an agreed upon protocol, a decision must be made. It should be clear what the choice will be. The protocol allows all options to be evaluated on a point by point basis, and if some of the aforementioned methods of comparison are used, the decision will be in a quantified form. This method insures all the critical points on each brand of equipment were thoroughly evaluated in a standard accepted manner. An organized approach to equipment purchasing such as described will decrease the chance for regrets later. Having made such a thorough evaluation will also ease writing of the justification for the equipment as most of the work is completed. The reasoning will also be much more difficult to dispute by management.

Once the purchase order has been written and approved, this organized method of evaluation shouldn't be abandoned. The equipment must still be inspected before acceptance and the second evaluation should be just as thorough as the first one. A written protocol should be used for evaluation based upon the production specifications agreed upon in the purchase order. These agreed upon production requirements should be evaluated by representa-

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tives of the purchasing company. For high speed packaging equipment, statistically valid tests should be designed to insure, for example, such aspects as correct fill weight are being met within the agreed upon rejection rate. With the cost of packaging equipment, this effort to insure all the specifications are met is justified. It is much more difficult to have problems solved after the equipment has left the vendor's factory. There is also the question of who will pay for the expenses as the equipment was already accepted. This is the finishing step to a well organized decision and should not be left out.

METHOD OF COMPARISON

A program of equipment evaluation and selection will involve the comparison and trade-off of a range of factors or criteria. The actual list will depend upon the initial goals for purchase and the magnitude of what is being evaluated. Some factors which may generally be applied to the selection of pharmaceutical equipment are:

Physical Appearance

Construction

Durability

Change Over

Cleanability

Validation/Calibration

Parts/Service/Warranty

User Experience

Cost

Safety

Type of Labor

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Development of a list of evaluation criteria is best accomplished as a group rather than compiled by a select few. All those affected by the decision making process should have input into the procedure. Agreement on the criteria is usually a minor step in the overall process. Where difficulty may arise, is in the discrimination among factors and the determination as to the relative importance of each item. How does one make a rational comparison between items that are different in nature and dimension? How does one incorporate all the factors into a framework which will provide an overall Equipment Measure (EM) which can be used as part of a final determination in the selection process? This is usually the point where the selection process breaks down because there appears to be no rational method for incorporating dissimilar factors into an overall equation for final selection.

A model which can be adopted to assist those involved in the evaluation procedure was developed by Brown-Gibson[1]. The model's original focus was in evaluating sites for potential plant location, yet can be used where many different factors need to be evaluated in a single framework. The model classifies criteria, quantifies factors, and forces the user to discriminate or make a trade-off among evaluation criteria.

The use of the Brown-Gibson model is initiated by taking the list of evaluation criteria and breaking them down into the following categories.

1. <u>Critical</u> - These are factors which if not present preclude the equipment from further consideration. In

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the case of selecting pharmaceutical equipment such factors as performance standards, safety, ability to meet GMP's, or availability of parts/service can be considered critical criteria. In a particular case involving the selection of high speed blister packaging machinery for several manufacturing sites around the world, vendors were eliminated from further consideration because they could not provide the parts/service to a particular location. Using the same example, other equipment was eliminated because it was too sophisticated for the skill level of the available labor force. Still others were eliminated because their electronic sophistication did not fit well with the unreliable power supply of a particular country. Power surges were a major problem in this part of the world.

In the case of safety, a preliminary inspection by a Safety Engineer may eliminate equipment before a major investment is made in evaluation costs. Critical factors properly identified can save significant time, money, and resources.

2. <u>Objective</u> - Factors which can be quantified, usually in monetary terms, are considered objective criteria. In select cases a factor can be considered as both objective and critical. The skill level of available labor might be considered a critical factor with the cost of such labor classified as objective criteria. This

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discrimination usually becomes more distinct as one becomes familiar with the model.

In selecting pharmaceutical equipment there are many cost factors which should be considered. Initial cost of machinery, start-up costs, energy consumption, cost of parts, and labor costs are just a select few.

For certain projects an in-depth cost analysis should be undertaken; for others, a simpler approach is adequate. Classifying the project into one of the following categories will help determine how much time and effort should be utilized in the cost analysis stage. It will also reveal what costs should be included in the analysis.

1. Replacement:maintenance
2. Replacement:cost reduction
3. Expansion of existing products or markets
4. Expansion into new products or markets
5. Safety or environment

Usually a more in-depth cost analysis is needed for cost reduction projects and expansion of product lines. Typically, large projects require more analysis than small ones. Capital budgeting can be used to evaluate cash flows over a future period of time. This will provide a more accurate picture of the costs involved in the investment of new equipment.

3. <u>Subjective</u> - Criteria which is qualitative in nature is considered subjective. This group of factors can be

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evaluated but not in monetary terms. Subjective factors in selecting pharmaceutical equipment might include construction, physical appearance, reputation of vendor, or other qualitative items. Noncritical safety factors can also be considered subjective criteria.

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THE MODEL

Once a group of evaluation points is agreed upon and classified into the three categories, the Brown-Gibson model can be utilized. For each piece of equipment an overall Equipment Measure, EM, is calculated which reflects the relative values of the individual factors. The following has been adopted from Brown-Gibson.

$$EM_i = CFM_i \times [X \times OFM_i + (1-X) \times SFM_i] \qquad \text{[EQ1]}$$

where CFM_i = the critical factor measure for equipment *i*

OFM_i = the objective factor measure for equipment *i*

SFM_i = the subjective factor measure for equipment *i*

X = the objective factor decision weight $(0 \leq X \leq 1)$

Critical factors can have a value of 0 or 1 based upon the machinery's ability to satisfy the criteria. A value of 1 is assigned if the equipment meets the criteria and a value of 0 if it does not. If any critical factor is 0 for a particular piece of equipment than the overall EM is 0 eliminating this item from further consideration.

The Objective Factor Measure, OFM, is based upon the costs associated with each piece of equipment. It is more difficult to calculate and involves the following formula:

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$$OFM_i = [OFC_i \times \sum_i (1/OFC_i)]^{-1} \qquad [EQ2]$$

where OFC_i = the total of all objective factor costs for equipment *i*

This equation assigns equipment with the lowest overall total cost the largest OFM. It also converts the objective costs to dimensionless units, thus allowing eventual comparison of objective and subjective criteria. To use the equation, total all objective costs for each piece of equipment under evaluation to determine the OFC. Take the reciprocal of this value. Add reciprocals for all equipment under consideration. Multiply the OFC for a specific piece of equipment by the sum of the reciprocals. The reciprocal of this value is the OFM. An example will clarify the relationships.

The subjective factor measure, SFM, for each piece of equipment is based upon relative weights assigned to each factor using preference theory and the weight of equipment *i* relative to all

TABLE 1

Cost to Produce 100,000 Units

Equipment	Material	Utilities	Labor	OFC Total	Reciprocal	OFM
1	$375	$73	$160	$608	.001645	.33217
2	415	91	120	626	.001597	.32261
3	335	75	175	585	.001709	.34522
					$\sum$.004951582	

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other pieces of equipment for each subjective factor. The SFM is calculated according to the following formula.

$$SFM_i = \sum_k (SFW_k \times EW_{ik}) \qquad [EQ3]$$

where SFW_k = the weight of subjective factor k in comparison to all subjective factors.

EW_{ik} = the weight of equipment i in comparison to other equipment for subjective factor k.

As stated, preference theory is utilized to discriminate and weight each of the subjective factors. Factors should be compared two at a time assigning the more important factor a value of 1 and the less important a value of 0. If no preference exists each factor is assigned a value of 1. This process can be carried out as a group but a better method to eliminate group dynamics is to utilize a personal computer. Software programs such as "Expert Choice" are available to assist the user in the comparison of variables. Once all factors are compared, the 1's are totaled for each factor. The factor weight is the factor sum divided by the total preference values for all factors. The sum of all factor weights should equal 1. Equipment weights are assigned in a similar fashion. The following example will clarify the process.

Lastly, the objective factor decision weight, X, must be determined. This factor determines the relative importance of objective versus subjective criteria. The value of X should be determined by the group involved and may be affected by corporate policy, management philosophy, or the goals for the evaluation process. An acceptable starting value would be 0.8. This would

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TABLE 2

Determining Subjective Factor Weights (SFW)

Factor	1vs2	1vs3	1vs4	2vs3	2vs4	3vs4	Total	SFW
1. Safety	1	1	1	--	--	--	3	.375
2. Ease of Maintenance	0	--	--	1	1	--	2	.250
3. Physical Appearance	--	0	--	0	--	1	1	.125
4. Warranty	--	--	0	--	1	1	2	.250
						Total Preference Value =	8	1.000

give the objective criteria 80% of the total weighting and the subjective criteria 20%. Once it is determined an overall Equipment Measure can be calculated. EM's can be plotted for different values of X thus giving the evaluation team an indication of the sensitivity of the model. The use of a suitable spreadsheet such as Lotus 1-2-3[2] will provide more flexibility and graphic capabilities to the analysis. It can also be used as a historical evaluation file.

CONCLUSION

The evaluation procedure outlined entails planning, organization and the dedication of valuable time in order to insure its success. As time is not an abundant commodity at most companies there is a tendency not to give the equipment selection process

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the full attention it warrants. In the pharmaceutical industry much consideration is given to standard procedures which insure the integrity, for example, of manufacturing processes, clinical studies, or laboratory equipment. This same attention to detail, however, is often not carried over into the equipment evaluation process. Unfortunately this lack of consideration can often have an adverse effect on the success of a project or on the corporation itself.

Once a commitment to a more organized process is made, a decision as to methods for evaluation will be needed. The Brown-Gibson model is one of many examples that are available. It shows the value of quantifying the array of subjective parameters that influence the decision process. These may then be used in conjunction with more readily quantified parameters to arrive at a more valid decision.

This methodical approach, although fallible, will decrease the risks when purchasing equipment. What often is an opinionated process will be turned into a scientific one which is only in keeping with the pharmaceutical industry.

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